

Appl. No. 09/759,056  
Amendment dated September 30, 2005  
Reply to Office Action of June 30, 2005

4) The Examiner rejected claims 102 and 103 as including new matter.  
Applicants respectfully traverse.

As discussed previously, Applicants have described a variant nucleic acid that has 99% sequence identity to a DNA molecule encoding a polypeptide comprising an amino acid sequence of SEQ ID NO:2 and that encodes an active Stra6 polypeptide. (para 0096, p 11) An active Stra6 polypeptide retains at least one biological or immunological function of a native or naturally occurring Stra6 polypeptide. (para 0131-0132, p 15) Applicants have described raising monoclonal antibodies to an amino acid sequence of 532 to 667 of SEQ ID NO:2. (See the specification at para 0429, p 46.) Applicants have further described that monoclonal antibodies to a human Stra6 protein detect expression of Stra6 on the cell surface of a colorectal cancer cell and that such expression is enhanced in response to retinoic acid. (para 0497, p 53)

Applicants submit that contrary to the Examiner's position, they have described and supported the subject matter of claims 102 and 103 and have not introduced new matter.

Applicants respectfully request withdrawal of the rejection on this basis.

Applicants submit the specification provides sufficient written description to show possession of the claimed invention, and respectfully request withdrawal of the 35 U.S.C. § 112, first paragraph, rejection.

#### 35 U.S.C. § 112, First Paragraph, Enablement

Claims 9 and 10 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. According to the Office Action, the specification, while being enabling for the nucleotide sequence of SEQ ID NO:1, does not reasonably provide enablement for polynucleotides having a certain degree of hybridization to the polynucleotide SEQ ID NO:1. The Examiner contends the claim language did not limit stringency of hybridization, and therefore allegedly encompassed a genus of

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polynucleotides capable of non-specific binding to SEQ ID NO:1 or any other polynucleotide. Applicants respectfully traverse the rejection.

Applicants contend that one of skill in the art reading this specification would be able to use a nucleic acid comprising at least 99% identity to a nucleotide that hybridizes to the complement of a nucleic acid that encodes a polypeptide comprising an amino acid sequence of SEQ ID NO:2 without undue experimentation. There are many factors to be considered in an analysis of enablement, including breadth of the claims, nature of the invention, the state of the prior art, the level of ordinary skill, level of predictability in the art, the amount of direction provided by the inventor and the existence of working examples, and the quantity of experimentation. MPEP 2164.01(a) citing *In Re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

The Examiner acknowledges that the specification is enabling for the nucleotide sequence of SEQ ID NO:1 (which encodes protein SEQ ID NO:2). (See the Office Action at page 6 , Section 6) In addition to the nucleotide sequence of SEQ ID NO:1, claim 9, as amended, and claim 10, depending from claim 9, also encompass polynucleotides encoding a PRO 10282 (Stra6) polypeptide comprising DNA that hybridizes under stringent conditions to the complement of the nucleic acid sequence that encodes amino acids 1 to 667 of SEQ ID NO:2. Applicants have described nucleic acid sequences comprising at least 900 nucleotides that hybridize to a nucleic acid sequence of nucleotide 49 to 2049 of SEQ ID NO:1 at para 0025, 0026; 0031, ( p 3-5). Applicants have provided the conditions for stringent hybridization at para 0113-0115, p 13. Applicants have provided an Example of using a probe at paras 0386-0389 (p 42, Example 2). Moreover, Applicants have demonstrated hybridization using a probe corresponding to nucleotides 432-1247 of the coding sequence of the human Stra6 polypeptides encoded by DNA 148380 2827 (PTA-1181). (See para 0472, p 50; Example 12.) Applicants submit that one of skill in the art would understand how to make and use the nucleic acid of claim 9 or claim 10 without undue experimentation. Thus, Applicants respectfully request withdrawal of the rejection on this basis.

Thus, Applicants submit that they have provided sufficient description to allow

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one of skill in the art to make and use the claimed nucleic acids, and respectfully request withdrawal of the 35 U.S.C. § 112, first paragraph, rejection.

**Double Patenting**

Applicant defers commenting on any provisional double patenting rejections until an actual rejection is presented.

**Request for an Interview**

Applicants request an interview with the Examiner. Upon receipt of this paper, Applicants request the Examiner contact Applicants' representative to schedule the interview.

**CONCLUSION**

In view of the above amendments and remarks, Applicants respectfully request a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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